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EXAMINER	
JANG, CHRISTIAN YONGKYUN	
ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
02/05/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/506,872	GIRON ET AL.	
	Examiner	Art Unit	
	CHRISTIAN Y. JANG	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-104 and 108-119* is/are pending in the application.

4a) Of the above claim(s) *110-119* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-104, 108, 109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendments/Remarks filed on July 16, 2008. Claims 66-104 and 108-119 are pending in the instant application. Claims 110-119 have been newly added. The Amendments to claims 66, 78-83, 95, and 108 are acknowledged by the examiner. The new title is accepted by the examiner.

Election/Restrictions

2. Newly submitted claims 110-119 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

3. Claims 113-116 are related to the original invention as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be practiced by another breath collection apparatus.

4. This application contains claims directed to the following patentably distinct species of claims 110-112 which involves the monitoring of a physiological parameter related to the metabolic rate of the subject and claims 117-119, involving the analysis of the collected samples in a remote location. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 110-119 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 108 and 109 are rejected under 35 U.S.C. 102(b) as being anticipated by Mault (USP #5,179,958).

8. As to claim 108, Mault teaches a method of determining, in a breath test of a subject, the change in volume of a species in the subject's breath, comprising the steps of: measuring a first volume of said species over a unit period of time (col 4, lines 42-46); measuring a first concentration of said species on the breath of the subject by means of said breath test (col 4, lines 55-57); measuring a second concentration of said species in the breath of the subject by means of said breath test (col 4, lines 55-57); monitoring a physiological parameter of the subject related to the metabolic rate of the subject, for change in said parameter between the measuring of said first concentration and said second concentration (col 4, lines 55-57); and adjusting said second concentration according to change determined in said physiological parameter, such

that said second concentration measured is representative of the volume of said species over said unit time in the subject's breath (col 4, lines 62-66).

9. As to claim 109, Mault teaches the physiological parameter of the subject is at least one of the pulse rate of the subject, the integrated area under a capnographic measurement of the subject's breath, and the breath flow rate of the subject (col 4, lines 62-66).

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 66-74, 76-79, 84-89, 91, 95, 96, 98-102, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) in view of Mottram (USP #6,488,635).

12. As to claim 66, Lemelson teaches a system for collecting a plurality of samples of breath of a subject (Abs) comprising: a breath conduit adapted to convey breath from the subject (11); a sensor for determining a characteristic of said breath exhaled from the subject (28), a plurality of sample containers for collection of said plurality of samples (20); a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (column 5, lines 30-35). Lemelson fails to teach a sample distributor which directs the samples according to the sensed characteristics of said exhaled breath. However, Mottram, in a breath collection system, teaches that the activation of the collection process can be made to activate

according to a sensed breath characteristic (col. 7, lines 16-21). As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by Lemelson with a collection activation setup taught by Mottram so that sample collection can be made only when necessary.

13. As to claim 67, Lemelson teaches a controller, where said different predetermined samples of said breath are directed to different ones of said plurality of sample containers according to said controller (column 5, 32-35).

14. As to claims 68 and 100, Lemelson discloses the invention substantially as claimed. Lemelson does not teach a sample distributor which is operated manually. However, Lemelson does disclose an automatic sample distributor and it would not be beyond the ability of one of ordinary skill in the art to utilize a manually operated sample distributor when the end result is equivalent.

15. As to claim 69, Lemelson teaches a system according to claim 66 wherein said sample distributor directs said samples at predetermined times (column 7, lines 47-52).

16. As to claims 70 and 85, Lemelson discloses the invention substantially as claimed. Lemelson does not teach that the predetermined times are at fixed time intervals. However, it is the examiner's position that it would not be beyond the ability of one of ordinary skill in the art to recognize that gas samples collected at fixed time intervals would allow comparative analysis without a time-dependent variable. Thus, it would be obvious to one of ordinary skill in the art to modify Lemelson with a fixed time interval mechanism in order to increase the accuracy of the device.

17. As to claim 71, Lemelson teaches the predetermined times are determined by a characteristic of said breath of the subject (column 7, lines 17-21).

18. As to claim 72, Lemelson teaches the characteristic of said breath is at least one of the carbon dioxide concentration, the oxygen concentration, the excess pressure, the temperature, the humidity, the flow rate and the sound of said breaths (column 6, line 65 to column 7, line 4).

19. As to claim 73, Lemelson teaches the predetermined times are determined by at least one physiological characteristic of the subject (column 6, lines 14-17).

20. As to claim 74, Lemelson teaches the at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (column 6, lines 14-17).

21. As to claim 76, Lemelson teaches the breath conduit comprises a breath tube through which the subject provides breath by blowing (11).

22. As to claim 77, Lemelson teaches a one-way check valve for directing said breath samples from said breath tube towards said plurality of sample containers (column 2, lines 27-31).

23. As to claim 78, Lemelson teaches the system comprises

a breath analyzer for determining a characteristic of said breath (column 6, lines 14-23); and

a valving system to select at least part of said breath for transfer to said sample a distributor, according to said characteristic of said breath (column 5, lines 39-42).

24. As to claim 79, Lemelson teaches the system comprises

a breath analyzer for determining a characteristic of said breath (column 6, lines 14-23); and

a valving system to select at least part of said breath for transfer to said sample distributor, according to said characteristic of said breath (column 5, lines 39-42).

25. As to claim 84, Lemelson teaches the controller causes said sample distributor to direct said samples at predetermined times (column 7, lines 47-52).

26. As to claim 86, Lemelson teaches the predetermined times are determined by a characteristic of said breaths of the subject (column 7, lines 17-21).

27. As to claim 87, Mottram teaches the characteristic of said breath is at least one of CO_2 concentration, O_2 concentration, excess pressure, temperature, humidity, flow rate, and sound of said breaths.

28. As to claim 88, Lemelson teaches the predetermined times are determined by a physiological characteristic of the subject (column 7, lines 16-21).

29. As to claim 89, Lemelson teaches the at least one physiological characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, blood pressure, gastric pH value and temperature (column 6, lines 14-17).

30. As to claim 91, Lemelson teaches at least one of said sample containers has rigid walls and is evacuated before collection of said samples (column 2, lines 39-46). Although Lemelson does not specify a container with rigid walls, the use of a technique to controllably flush and clean residual gas is indicative of a container that has not started out deflated, and thus has the rigidity to sustain an internal volume or space.

31. As to claim 95, Lemelson teaches a system for collecting a plurality of samples of breath of a subject comprising: a breath conduit adapted to convey breath from the subject (11); a valving system (col 5, lines 39-42); a plurality of sample containers for collection of said plurality of samples (20); and a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (col 5, 30-35). Lemelson fails to teach a valving system which directs the samples according to the sensed characteristics of said exhaled breath. However, Mottram, in a breath collection system, teaches that the activation of the collection process can be made to activate only when a breath characteristic is within acceptable ranges ([0023]). As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by Lemelson with a collection activation setup taught by Mottram so that sample collection can be made only when necessary.

32. As to claim 96, Lemelson teaches the at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (col 6, lines 14-17).

33. As to claim 98, Lemelson teaches said breath conduit comprises a breath tube (11).

34. As to claim 99, Lemelson teaches a pressure sensor for determining the pressure of said breath (Abs), and wherein said valving system is actuated according to said pressure of said breath (col 2, lines 32-39).

35. As to claim 101, Lemelson teaches a controller causing said sample distributor to direct said different predetermined samples to said different ones of said plurality of sample containers (74).

36. As to claim 102, Lemelson teaches the controller prompts the subject at predetermined times to provide breath by blowing (col 8, lines 46).

37. As to claim 104, Lemelson teaches at least one of said sample containers has rigid walls and is evacuated before collection of said samples (col 2, lines 39-46).

38. Claims 75 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Mottram (USP #6,488,635) as applied to claims 66 and 95 above, and further in view of Dietz (USP #5,005,571).

39. As to claim 75 and 97, Lemelson and Mottram discloses the invention substantially as claimed. However, Lemelson and Mottram does not disclose a breath conduit in the form of an oral/nasal cannula.

Dietz teaches a oral/nasal cannula (Abs) for the purpose of use in a breathing monitoring apparatus (Abs).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a breath collection device taught by Lemelson having a collection activation setup taught by Mottram to employ a cannula as taught by Dietz in order to allow for the use of the device where the user no longer has to actively engage the device.

40. Claims 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Mottram et al. (USP #5,797,885) as applied to claim 78 above, and further in view of Hoberman (USP #5,159,934).

41. As to claims 80 and 81, Lemelson discloses the invention substantially as claimed. Although Lemelson discloses various chemical, photoelectric, and bio-sensors, neither Lemelson nor Mottram specifically disclose a capnographic analyzer.

Hoberman teaches a miniature sensor for capnography (Abs) for the purpose of rapid, up-to-date readings of CO_2 concentration in the patient air stream (Abs). In addition, the examiner notes that the analysis of CO_2 gas from patient exhaled breath is one of the most common and well known analytical techniques for patient respiration diagnosis including some forms of lung disease and various other conditions.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a breath collection device taught by Lemelson having a collection activation setup taught by Mottram with a capnography sensor taught by Hoberman in order to specify the use of the device for the analysis of CO_2 concentration.

42. As to claim 82, a capnography sensor, as taught by Hoberman, by definition measures the carbon dioxide concentration.

43. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Mottram et al. (USP #5,797,885), and Hoberman (USP

#5,159,934) as applied to claim 82 above, and in further view of Casparie et al. (USP #5,069,220).

44. As to claim 83, Lemelson, Mottram, and Hoberman discloses the invention substantially as claimed. However, Lemelson, Mottram, and Hoberman do not disclose a system where breath is collected when CO_2 concentration is at the plateau value of its waveform, such that alveolar air is sampled.

Casparie teaches the use of exhaled breath when carbon dioxide concentration reaches a plateau level (col 1, lines 21-23) for the purpose of most accurate determination of blood gas concentration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a breath collection device taught by Lemelson, having a collection activation setup taught by Mottram and a capnography sensor taught by Hoberman to begin collection when carbon dioxide level reaches a plateau as taught by Casparie in order to increase the accuracy of the device.

45. Claims 90 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Mottram et al. (USP #5,797,885), as applied to claims 66 and 95 above, and further in view of Opekun, Jr. et al. (USP #5,140,993).

46. As to claims 90 and 103, Lemelson and Mottram discloses the invention substantially as claimed. However, Lemelson and Mottram do not disclose a sample container in the form of a flexible bag.

Opekun teaches a flexible, inflatable plastic bag (Abs) for the purpose of collecting a breath sample.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a breath collection device taught by Lemelson having a collection activation setup taught by Mottram with an inflatable plastic bag as taught by Opekun which would allow the means for collection to be kept to a minimal volume prior to deployment.

47. Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885), Mottram et al. (USP #5,797,885), and Hoberman (USP #5,159,934) as applied to claim 80 above, and further in view of Daniels et al. (USP #6,099,481).

48. As to claim 92, Lemelson, Mottram, and Hoberman discloses the invention substantially as claimed. However, Lemelson, Mottram, and Hoberman do not disclose a valving system adapted to direct breath exhaled when said CO_2 concentration is at the plateau into one of said containers and breath inhaled when said CO_2 concentration is at the baseline into a second one of said sample containers.

Daniels teaches respiratory measurements which includes carbon dioxide elimination, airway dead space, and physiologic dead space which clearly shows the plateau during exhalation and the baseline for inhalation for the purpose of deciphering the volume of CO_2 elimination and alveolar volume (col 8 line 61 to col 9 line 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the breath collection device taught by Lemelson, a collection activation setup taught by Mottram, and the capnography sensor taught by Hoberman to capture breath samples during these baseline and plateau periods in order to enable to machine to decipher such physiological parameters as CO_2 elimination and alveolar volume as taught by Daniels.

49. As to claim 93, Lemelson, Mottram, Hoberman, and Daniels disclose the invention substantially as claimed. Lemelson teaches sample containers which absorb a predetermined gas of said breath of the subject (col 6, lines 37-43). Lemelson, Mottram, Hoberman, and Daniels fail to teach a heater for expelling said predetermined gas of said breath of the subject. However, Lemelson recognizes the importance of cleaning out the chambers, utilizing a water trap and flushing mechanism to clean out the chambers (Fig. 2, 29). In addition, the expulsion of gas from a container by means of using the properties of thermal expansion is a well known technique in the field. It is the examiner's position that it would not be beyond the ability of one of ordinary skill in the art to modify the breath collection device taught by Lemelson, a collection activation setup taught by Mottram, and the capnography sensor taught by Hoberman with a heated chamber in order to remove residual sample gas molecules which may adversely affect future usage of the container as an alternative to the existing liquid/water trap.

50. As to claim 94, Lemelson, Hoberman, and Daniels disclose the invention substantially as claimed. Lemelson teaches that said predetermined gas is a volatile

organic compound. Although Lemelson does not explicitly state the phrase “volatile organic compound”, the examiner notes that there is no limiting definition within the applicant’s disclosure as to the limitations of the phrase. Thus, the examiner is taking the broadest reasonable definition of the phrase, in light of the disclosure, wherein “volatile organic compound” may mean any substance detectable from human expired breath that has high enough vapor pressure to vaporize into a gaseous form. Since Lemelson discloses that his teachings can be used to automatically analyze the chemical contents within the breath of living beings for analysis of a variety of conditions and diseases of said living being, the examiner regards Lemelson to teach the limitations of the claim.

Response to Arguments

51. Applicant's arguments with respect to claims 66-104 have been considered but are moot in view of the new ground(s) of rejection.

52. Applicant's arguments to claims 108 and 109, rejected under 35 U.S.C. 102(b) as being anticipated by Mault, filed July 16, 2008 have been fully considered but they are not persuasive.

53. As to claim 108, applicant has argued that because Mault teaches the direct assessment of volume, while applicant’s invention takes a single measurement of the volume that Mault fails to anticipate the claim. However, Mault's disclosure still results in a second concentration that is representative of the volume of said species, and as such, the argument is unpersuasive. Claim 109 is rejected accordingly.

54. Claims 105-107 have been cancelled and the new claims have been withdrawn due to election by election by original presentation. As such, a discussion on the definition of volatile organic compounds may be moot. However, the examiner would like to point out that volatile organic compounds are not limited to a definition of "a group of chemicals whose effects have serious repercussions both on the environment, and on the health to those exposed thereto". The most simplistic definition is any organic chemical compound with high enough vapor pressure under normal conditions to significantly vaporize and enter the atmosphere. Since applicant has provided no explicit or limiting definition of what comprises a VOC, this is the definition that the examiner is using for purposes of examination.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3735
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